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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/003,996 | 11/15/2001 | Peter M. Bonutti | BON-1360-8 | 8298 |

33771 7590 10/04/2007
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| EXAMINER |
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HOFFMAN, MARY C

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| ART UNIT | PAPER NUMBER |
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3733

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| MAIL DATE | DELIVERY MODE |
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10/04/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/003,996

Applicant(s)

BONUTTI, PETER M.

Examiner

Mary Hoffman

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 51-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 36-44, 46-47, 49, 57-60 and 69-76 is/are allowed.
- 6) ☒ Claim(s) 51-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 7/27/2007.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/26/2007 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 53-55 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Leary (U.S. Patent No. 5,073,373) in view of Kambin (U.S. Patent No. 4,573,448).

O'Leary discloses A surgical procedure to be conducted on a patient, said surgical procedure comprising the steps of inserting a first tubular member into a patient's body, moving body tissue from a first location in the patient's body through the first tubular member to a location outside of the patient's body, inserting a second

Art Unit: 3733

tubular member into a second patient's body, and moving at least a portion of the body tissue through the second tubular member to a second location in the second patient's body, wherein a substance is added to the body tissue after moving the body tissue from the first location through the first tubular member to a location outside of the patient's body and prior to moving the body tissue through the second tubular. {O'Leary discloses using allogenic bone}

O'Leary discloses the claimed invention except for the body tissue being re-implanted into the same patient, i.e. using autogenic bone, and the first tubular member used to cut the tissue from the first location.

First of all, it would have further been obvious to use autogenic bone (meaning that the bone is taken from the patient and then re-implanted into the patient) rather than allogenic bone since the Supreme Court has recently found that where there is a "design need or market pressure and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product is not of innovation but of ordinary skill and common sense." *KSR v. Teleflex*, 550 U.S. __ (2007). The design need for autogenic bone is due to the well-known need for compatible bone with a patient's tissue, and it is well known that autogenic bone provides optimum compatibility with the patient's body since it is originally from the patient. Also, clearly, a finite number of solutions (autogenic, allogenic, or xenogenic bone) exist. Therefore, it would have been obvious to one of ordinary skill in the art to substitute allogenic with autogenic bone.

Art Unit: 3733

Kambin teaches a tissue-cutting instrument that provides a rotatable cutter and suction (Column 3 lines 47-56).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method of O'Leary with the cutter of Kambin since Kambin's cutter is used to remove tissue fragments, which can be modified in the method of O'Leary which cuts and removes tissue fragments in order to make the desired bone paste.

Claims 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over O'Leary ' 373 in view of Kambin '448 as applied above, and further in view of Muller-Lierheim (U.S. Patent No. 4,828,563) and Amrani (U.S. Patent No. 4,210,580).

O'Leary, as modified, discloses the closed invention except for centrifuging the blood or body tissue to separate one or more components from the blood.

Muller-Leirheim teaches that growth factors, particularly fibronectin, are added to bone implants to enhance biocompatibility and mechanical strength (Column 1 line 37-Column 2 line 7). Amrani teaches that fibronectin may be obtained from blood plasma by centrifuging the blood plasma (Column 2 lines 26-30).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method of O'Leary with the additional step of centrifuging blood to obtain fibronectin in view of Muller-Leirheim and Amrani, an additive to an implant material, to enhance the biocompatibility and strength of the O'Leary implant material.

Response to Arguments

Applicant's arguments filed 07/26/2007 have been fully considered but they are not persuasive.

While the examiner agrees with Applicant that O'Leary discloses allogenic bone rather than autogenic bone, the examiner asserts that this would be an obvious change as explained in the above 35 U.S.C. 103(a) rejection. It is again noted that it was well-known to use both allogenic, xenogenic, and autogenic sources of tissue interchangeably at the time the invention was made. The fact that O'Leary doesn't mention autogenic bone and states that allogenic bone is not considered as "teaching away", as suggested by Applicant. Applicant is merely teaching a better or another way in stating that allogenic bone is preferable.

In response to Applicant's argument that O'Leary in view of Kambin does not include certain features of Applicant's invention, the limitations on which the Applicant relies (i.e., that the body tissue re-implanted into the body would not include cells) are not stated in the claims. Therefore, it is irrelevant whether the reference includes those features or not. It is noted that claim 53 requires "moving body tissue from a first location in a patient's body..." Clearly, removing tissue from the body will result in the tissue containing some cells. It is irrelevant that after pulverizing and demineralizing the removed body tissue the cells would be lysed, because the claim does not require that the re-implanted body tissue also contains cells. Rather, the claim merely states that "the body tissue includes cells." Since the body tissue of O'Leary includes cells prior to being pulverized and demineralized, it meets the claims as currently recited.

The rejections are deemed proper.

Allowable Subject Matter

Claims 36-44, 46-47, 49, 57-60 and 69-76 allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary Hoffman whose telephone number is 571-272-5566. The examiner can normally be reached on Monday-Friday 9:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

mch


EDUARDO C. ROBERT
SUPERVISOR SENIOR EXAMINER